Claim Amendments

Claims 1-58 (canceled).

Claim 59 (currently amended). A method comprising administering a therapeutically effective amount of a composition ~~comprising~~ wherein the anti-HIV ingredients in the composition consist of [2-(6-amino-purin-9-yl)-1-methyl-ethoxymethyl]-phosphonic acid diisopropoxycarbonyloxymethyl ester fumarate (tenofovir disoproxil fumarate) and (2*R*, 5*S*, cis)-4-amino-5-fluoro-1-(2-hydroxymethyl-1,3-oxathiolan-5-yl)-(1H)-pyrimidin-2-one (emtricitabine) to a patient in need of antiviral therapy consisting of anti-HIV therapy.

Claim 60 (canceled).

Claim 61 (currently amended). The method of claim ~~60~~ 59 wherein the composition comprises about 300 mg of tenofovir disoproxil fumarate and about 200 mg of emtricitabine.

Claim 62 (original). The method of claim 59 wherein the amount of the total tenofovir disoproxil fumarate and emtricitabine in the composition in relation to carrier material is about 5% to about 95% of the total composition (weight:weight, exclusive of coating).

Claim 63 (original). The method of claim 59 wherein tenofovir disoproxil fumarate and emtricitabine are present in a tablet.

Claim 64 (original). The method of claim 63 wherein tenofovir disoproxil fumarate and emtricitabine are present in an amount of 300 mg and 200 mg respectively.

Claim 65 (canceled).

Claim 66 (original). The method of claim 62 wherein the weight ratio of the total of tenofovir disoproxil fumarate and emtricitabine in the composition in relation to ingredients other than tenofovir disoproxil fumarate and emtricitabine is 50:50 (excluding coating).

Claim 67 (original). The method of claim 66 wherein the composition comprises in weight percent (excluding coating) tenofovir disoproxil fumarate 30, emtricitabine 20, pregelatinized starch 5, croscarmellose sodium 6, lactose monohydrate 8, microcrystalline cellulose 30, magnesium stearate 1.

Claim 68-69 (canceled).

Claim 70 (original). The method according to claim 59 wherein the composition further comprises a pharmaceutically acceptable glidant.

Claim 71 (original). The method according to claim 70 wherein the glidant is selected from silicon dioxide, powdered cellulose, microcrystalline cellulose, metallic stearates, sodium aluminosilicate, sodium benzoate, calcium carbonate, calcium silicate, corn starch, magnesium carbonate, asbestos free talc, stearowet C, starch, starch 1500, magnesium lauryl sulfate, magnesium oxide, and formulations thereof.

Claim 72 (original). The method according to claim 71 wherein the metallic stearates are selected from calcium stearate, magnesium stearate, zinc stearate, and formulations thereof.

Claim 73 (currently amended). A pharmaceutical formulation ~~comprising~~ wherein the anti-HIV ingredients in the formulation consist of [2-(6-amino-purin-9-yl)-1-methyl-ethoxymethyl]-phosphonic acid diisopropoxycarbonyloxymethyl ester

fumarate (tenofovir disoproxil fumarate) and (2*R*, 5*S*, cis)-4-amino-5-fluoro-1-(2-hydroxymethyl-1,3-oxathiolan-5-yl)-(1H)-pyrimidin-2-one (emtricitabine).

Claim 74 (orginal). The pharmaceutical formulation according to claim 73 further comprising one or more pharmaceutically acceptable carriers or excipients.

Claim 75 (original). The pharmaceutical formulation according to claim 74 wherein the pharmaceutically acceptable carriers or excipients are selected from pregelatinized starch, croscarmellose sodium, povidone, lactose monohydrate, microcrystalline cellulose, and magnesium stearate, and formulations thereof.

Claim 76 (currently amended). The pharmaceutical formulation according to claim 74 wherein the amount of the total tenofovir disoproxil fumarate and emtricitabine in the formulation in relation to carrier and excipient material (weight:weight, excluding coating) is about 5% to about 95% ~~(weight ratio 0.08).~~

Claim 77 (original). The pharmaceutical formulation according to claim 76 wherein the weight ratio of tenofovir disoproxil fumarate and entricitabine together: total carrier and excipient in the formulation (excluding coating) is 500:1000, 400:900, 325:825, 225:725, 200:700, 500:700, 500:670, 500:763, 500:2840 or 500:2270.

Claim 78 (original). The pharmaceutical formulation according to claim 77 wherein the weight ratio (excluding coating) is 0.50, 0.44, 0.39, 0.31, 0.29, 0.71, 0.75, 0.65, 0.18 or 0.22.

Claim 79 (currently amended). The pharmaceutical formulation according to claim 76 wherein the weight ratio <u>of tenofovir disoproxil fumarate and emtricitabine together: total carrier and excipient in the formulation</u> (excluding coating) is from 0.18 to 0.75.

Claim 80 (original). The pharmaceutical formulation according to claim 73 in pharmaceutical dosage form.

Claim 81 (original). The pharmaceutical formulation according to claim 80 wherein the pharmaceutical dosage form is a tablet.

Claim 82 (original). The pharmaceutical formulation according to claim 73 wherein tenofovir disoproxil fumarate and emtricitabine are present in a ratio of about 300:200 by weight.

Claim 83 (currently amended). The pharmaceutical formulation according to claim 82 ~~comprising about 300 mg of~~ wherein the amounts of tenofovir disoproxil fumarate and ~~about 200 mg of~~ emtricitabine [[.]] are 30mg and 200mg respectively.

Claim 84 (original). The pharmaceutical formulation according to claim 73 suitable for oral administration.

Claim 85 (original). The pharmaceutical formulation according to claim 84 wherein the pharmaceutical dosage form is a capsule.

Claim 86 (original). The pharmaceutical formulation according to claim 73 suitable for administration once per day to an infected human.

Claim 87 (currently amended). A patient pack comprising (a) at least one coformulated pharmaceutical formulation ~~comprising~~ wherein the anti-HIV active ingredients in the anti-HIV formulation consist of [2-(6-amino-purin-9-yl)-1-methyl-ethoxymethyl]-phosphonic acid diisopropoxycarbonyloxymethyl ester fumarate

(tenofovir disoproxil fumarate) and (2*R*, 5*S*, cis)-4-amino-5-fluoro-1-(2-hydroxymethyl-1,3-oxathiolan-5-yl)-(1H)-pyrimidin-2-one (emtricitabine), and (b) an information insert containing directions for the use of tenofovir disoproxil fumarate and emtricitabine in formulation for the treatment of a patient in need of ~~antiviral~~ anti-HIV treatment ~~consisting of anti-HIV therapy.~~

Claim 88 (currently amended). The patient pack according to claim 87 wherein the pharmaceutical dosage form is a tablet, caplet, or capsule ~~comprising 300 mg~~ wherein the amounts of tenofovir disoproxil fumarate ~~and 200 mg of~~ emtricitabine are 300mg and 200mg respectively.

Claim 89 – 95 (canceled).

Claim 96 (currently amended). An oral pharmaceutical dosage form ~~comprising~~ wherein the anti-HIV active ingredients in the dosage from consist of tenofovir disoproxil fumarate, emtricitabine and Sustiva.

Claim 97 (canceled).

Claim 98 (currently amended). A tablet ~~comprising~~ wherein the anti-HIV ingredients in the tablet consist of 300 mg of tenofovir disoproxil fumarate, and 200 mg of emtricitabine ~~and~~ , together with carriers and/or excipients sufficient to produce less than 5% acid degradation of tenofovir disoproxil fumarate or emtricitabine after six months storage with desiccant at 40°C/25% relative humidity.

Claim 99 (currently amended). An oral dosage form ~~comprising~~ wherein the anti-HIV ingredients in the dosage form consist of Sustiva, 300 mg tenofovir disoproxil fumarate [[,]] and 200 mg of ~~emtriva and~~ emtricitabine , together with pharmaceutically acceptable carriers ~~or~~ and/or excipients.

Claim 100 (new). A method comprising administering a therapeutically effective amount of a composition wherein the anti-HIV active ingredients in the

composition consist of Sustiva, [2-(6-amino-purin-9-yl)-1-methyl-ethoxymethyl]-phosphonic acid diisopropoxycarbonyloxymethyl ester fumarate (tenofovir disoproxil fumarate) and (2*R*, 5*S*, cis)-4-amino-5-fluoro-1-(2-hydroxymethyl-1,3-oxathiolan-5-yl)-(1H)-pyrimidin-2-one (emtricitabine) to a patient in need of anti-HIV therapy.

Claim 101 (new). The method of claim 100 wherein the composition comprises about 300 mg of tenofovir disoproxil fumarate and about 200 mg of emtricitabine.

Claim 102 (new). The method of claim 100 wherein the amount of the total tenofovir disoproxil fumarate and emtricitabine in the composition in relation to carrier material is about 5% to about 95% of the total composition (weight:weight, exclusive of coating).

Claim 103 (new). The method of claim 100 wherein the composition is a tablet.

Claim 104 (new). The method of claim 103 wherein tenofovir disoproxil fumarate and emtricitabine are present in an amount of 300 mg and 200 mg respectively.

Claim 105 (new). The method of claim 102 wherein the weight ratio of the total of tenofovir disoproxil fumarate and emtricitabine in the composition in relation to ingredients other than tenofovir disoproxil fumarate and emtricitabine is 50:50 (excluding coating).

Claim 106 (new). The method according to claim 100 wherein the composition further comprises a pharmaceutically acceptable glidant.

Claim 107 (new). The method according to claim 106 wherein the glidant is selected from silicon dioxide, powdered cellulose, microcrystalline cellulose, metallic stearates, sodium aluminosilicate, sodium benzoate, calcium carbonate, calcium silicate, corn starch, magnesium carbonate, asbestos free talc, stearowet C, starch, starch 1500, magnesium lauryl sulfate, magnesium oxide, and formulations thereof.

Claim 108 (new). The method according to claim 107 wherein the metallic stearates are selected from calcium stearate, magnesium stearate, zinc stearate, and formulations thereof.

Claim 109 (new). A pharmaceutical formulation wherein the anti-HIV active ingredients in the formulation consist of Sustiva, [2-(6-amino-purin-9-yl)-1-methyl-ethoxymethyl]-phosphonic acid diisopropoxycarbonyloxymethyl ester fumarate (tenofovir disoproxil fumarate) and (2*R*, 5*S*, cis)-4-amino-5-fluoro-1-(2-hydroxymethyl-1,3-oxathiolan-5-yl)-(1H)-pyrimidin-2-one (emtricitabine).

Claim 110 (new). The pharmaceutical formulation according to claim 109 further comprising one or more pharmaceutically acceptable carriers or excipients.

Claim 111 (new). The pharmaceutical formulation according to claim 110 wherein the pharmaceutically acceptable carriers or excipients are selected from pregelatinized starch, croscarmellose sodium, povidone, lactose monohydrate, microcrystalline cellulose, and magnesium stearate, and formulations thereof.

Claim 112 (new). The pharmaceutical formulation according to claim 110 wherein the amount of the total tenofovir disoproxil fumarate and emtricitabine in the formulation in relation to carrier and excipient material (weight:weight, excluding coating) is about 5% to about 95%.

Claim 113 (new). The pharmaceutical formulation according to claim 112 wherein the weight ratio of tenofovir disoproxil fumarate and emtricitabine together: total carrier and excipient in the formulation (excluding coating) is 500:1000, 400:900, 325:825, 225:725, 200:700, 500:700, 500:670, 500:763, 500:2840 or 500:2270.

Claim 114 (new). The pharmaceutical formulation according to claim 113 wherein the weight ratio (excluding coating) is 0.50, 0.44, 0.39, 0.31, 0.29, 0.71, 0.75, 0.65, 0.18 or 0.22.

Claim 115 (new). The pharmaceutical formulation according to claim 112 wherein the weight ratio of tenofovir disoproxil fumarate and emtricitabine together: total carrier and excipient in the formulation (excluding coating) is from 0.18 to 0.75.

Claim 116 (new). The pharmaceutical formulation according to claim 109 in pharmaceutical dosage form.

Claim 117 (new). The pharmaceutical formulation according to claim 116 wherein the pharmaceutical dosage form is a tablet.

Claim 118 (new). The pharmaceutical formulation according to claim 109 wherein tenofovir disoproxil fumarate and emtricitabine are present in a ratio of about 300:200 by weight.

Claim 119 (new). The pharmaceutical formulation according to claim 118 comprising about 300 mg of tenofovir disoproxil fumarate and about 200 mg of emtricitabine.

Claim 120 (new). The pharmaceutical formulation according to claim 109 suitable for oral administration.

Claim 121 (new). The pharmaceutical formulation according to claim 120 wherein the pharmaceutical dosage form is a capsule.

Claim 122 (new). The pharmaceutical formulation according to claim 109 suitable for administration once per day to an infected human.

Claim 123 (new). A patient pack comprising (a) at least one coformulated anti-HIV pharmaceutical formulation wherein the anti-HIV active ingredients in the formulation consist of Sustiva, [2-(6-amino-purin-9-yl)-1-methyl-ethoxymethyl]-phosphonic acid diisopropoxycarbonyloxymethyl ester fumarate (tenofovir disoproxil fumarate) and (2*R*, 5*S*, cis)-4-amino-5-fluoro-1-(2-hydroxymethyl-1,3-oxathiolan-5-yl)-(1H)-pyrimidin-2-one (emtricitabine), and (b) an information insert containing directions for the use of tenofovir disoproxil fumarate, emtricitabine and Sustiva in formulation for the treatment of a patient in need of antiviral treatment.

Claim 124 (new). The patient pack according to claim 123 wherein the pharmaceutical dosage form is a tablet, caplet, or capsule wherein the amounts of tenofovir disoproxil fumarate and emtricitabine are 300mg and 200mg respectively.

Claim 125 (new). A tablet wherein the anti-HIV active ingredients in the tablet consist of Sustiva, 300 mg of tenofovir disoproxil fumarate and 200 mg of emtricitabine, together with carriers and/or excipients sufficient to produce less than 5% acid degradation of tenofovir disoproxil fumarate or emtricitabine after six months storage with desiccant at 40°C/25% relative humidity.

Respectfully Submitted,

Mark L. Bosse, Reg. No. 35,071
Gilead Sciences, Inc.
333 Lakeside Drive
Foster City, CA 94404.
Telephone: *(650) 522-5569*
Facsimile: *(650) 522-5575*
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